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Election 1638

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

**Luke Mankin & Bryan McKersie**

Serial No. **09/940,550**

Filed: **August 27, 2001**

For: **SELF-EXCISING POLYNUCLEOTIDES  
AND USES THEREOF**

Art Unit: 1638

Examiner: **David Fox**

**RESPONSE TO ELECTION/RESTRICTION REQUIREMENT**

**RECEIVED**

Commissioner for Patents  
Washington, D.C. 20231

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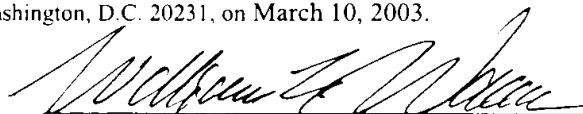
TECH CENTER 1600/2900

Sir:

In response to the Election/Restriction Requirement mailed on February 10, 2003, a response to which is due March 10, 2003, Applicant elects, with traverse, Group I directed to Claims 1-9, 21-25, 27, and 30-38 -36 as they relate to methods of using a polynucleotide comprising a recombinase-encoding gene and another gene encoding a trait of interest under the control of a promoter, all flanked by recombinase-recognition sites, to obtain transformed plants and the resultant plants.

Applicant makes the above election with traverse. Applicant submits that the invention is a novel polynucleotide and method for introducing self-excising polynucleotides into eukaryotic cells, and the transgenic plants and tissues generated therefrom. The novelty of the invention lies at least in the use of an isolated excisable polynucleotide comprising a desired trait polynucleotide and a

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William L. Warren - Reg. 36,714

recombinase polynucleotide operably linked to a promoter, all flanked by a pair of directly oriented recombination sites, whereby the recombinase activity is regulatable. This novel method allows for the production of a transgenic plant wherein an incorporated trait and other linked transgenic polynucleotides can be removed to restore the original genetic configuration of the plant's genome, which benefits are not provided in the prior art.

The Office Action states that restriction is required between the different inventions because "the different inventions have different functions or different effects." Specifically, the Office Communication states that the invention of Group I requires somatic tissue-specific promoters and methods of evaluating gene expression in somatic tissues such as roots or tubers. The inventions of Groups I, IV and VI require specific intron-containing recombinase genes. The invention of Group II requires seed- or seedling-specific promoters and methods for evaluating female sterility, seedlessness, or germinant lethality. The invention of Group III requires pollen-specific promoters and methods of evaluating male sterility. The invention of Group IV requires stress- or pathogen inducible promoters, methods of administering environmental stresses or pathogen challenges, and methods of evaluating resistance to environmental stresses or pathogens. The invention of Group V requires transactivator genes, and repressor-recognition sequences. The invention of Group VII requires multiple recombinase constructs, multiple recombinase-recognition sequences, and methods of their use. The inventions of Groups I-V require plant transformation and regeneration methods, not required by Groups VI and VII. Further, Groups I and VI are alleged to be distinct since Group VI can be used in a materially different process, such as the excision of another gene under the control of a constitutive promoter in an animal cell, or the in vitro production of recombinase protein.

Applicant respectfully submits that the restriction requirement does not meet the requirements set out in Chapter 800 of the MPEP, and accordingly requests that the Examiner review

and withdraw the requirement. Section 803.01 of the MPEP states that there are two requirements for restriction between patentably distinct inventions: 1) the inventions must be independent or distinct as claimed and 2) there must be a serious burden on the examiner if restriction is required. Applicant first submits that the Examiner has not demonstrated that it would be a serious burden to search and examine all of the claims together. Four of the seven groups of claims are within the same class, and therefore, easily searched together. Two of the other groups are within the same class, and therefore, also easily searched together.

Applicant additionally traverses the assertion the different inventions have different functions and different effects. The function of the inventions are to use an isolated excisable polynucleotide comprising a desired trait polynucleotide and a recombinase polynucleotide operably linked to a regulatable promoter, all flanked by a pair of directly oriented recombination sites, to allow for the production of a transgenic plant and the subsequent excision of the incorporated trait and other linked transgenic polynucleotides. The effect of the inventions are to restore the original genetic configuration of the plant's genome, in at least certain of the tissue of the plants. The function and effect of the inventions are not changed by the use of different types of promoters.

Applicant further submits that at least the restriction requirement between Groups I-V is improper. MPEP §809.02 states that the Examiner can require election of a species. In the present application, the Examiner is requiring restriction of a species. Applicant hereby submits that the restriction requirement is improper, and that the issuance of an election requirement would be proper as explained below.

The claims of Groups I-V are all dependent on Claims 1 and 30, currently placed into Group I. Claims 1 and 30 are independent genus claims that are directed to a method of using a

polynucleotide comprising a recombinase-encoding gene and another gene encoding a trait of interest under the control of a regulatable promoter, flanked by recombinase-recognition sites to obtain transformed plants, and the resultant plants. The remainder of the claims in Groups I-V are dependent on Claims 1 and 30 and are claims encompassing different species of regulatable promoters: the claims of Group I comprise the use of a somatic tissue promoter; the claims of Group II comprise the use of a seed-specific or germination-specific promoter; the claims of Group III comprise the use of a pollen-specific promoter; the claims of Group IV comprise the use of a pathogen or heat-induced promoter; and the claims of Group V comprise the use of a chemically-repressible promoter. The different types of regulatable promoters are representative species of the genus of regulatable promoter encompassed by Claims 1 and 30.

Claims 1 and 30 are independent genus claims that link the Groups I-V. A reasonable number of species may be claimed in one application if they are related (MPEP §806.04). Here, the different species of promoters are related. All of the species are regulatable promoters that may be used in the disclosed construct to regulate the expression of the recombinase-encoding gene and therefore allow for the excision of the polynucleotide. Furthermore, Groups I-V are related through their dependency on independent Claims 1 and 30. 37 C.F.R. §§ 1.141 and 1.146 permit a reasonable number of species to be claimed together in one application without restriction ; and five is generally considered to be a reasonable number of species for prosecution together in one application. Search and examination of all species would therefore not present an undue burden on the Examiner.

If the Examiner requires election among the species of promoter as discussed herein, Applicant further submits that the species are joined by linking generic Claims 1 and 30. Applicant submits that pursuant to MPEP §809.03, the Examiner could issue a conditional restriction of Groups II-V subject to the allowance of Claim 1 or Claim 30. Moreover, once a generic claim is allowed, all of the

claims drawn to species that contain all of the limitations of the generic claim are ordinarily allowable. Therefore if Claims 1 and 30 are allowed, the claims that are dependent upon these generic claims should also be allowable since they contain all of the limitations of the generic claims.

In summary, Applicant makes the above election with traverse. Applicant submits that each of the restrictions is improper and respectfully requests that the Examiner review and withdraw each restriction requirement. The foregoing is submitted as a full and complete Response to the Office Action mailed February 10, 2003. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 19-5029. The Examiner is invited and encouraged to contact the undersigned attorney of record if such contact will facilitate an efficient examination and allowance of the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William L. Warren', with a long horizontal flourish extending to the right.

By: William L. Warren  
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